



Schering-Plough
HealthCare Products

August 30, 1999

Schering-Plough Corporation
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Dockets Management Branch, HFD-305
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

**SUBJECT: Citizen Petition for Clotrimazole 1% as a Topical Antifungal Drug
Docket No. 96P-0460**

Dear Sir or Madam:

Reference is made to our citizen petition submitted November 27, 1996 to amend the Final Monograph for Topical Antifungal Drug Products for Over-the-Counter Human Use as published in the Federal Register on September 23, 1993.

In the citizen petition Schering-Plough HealthCare Products (SPHCP), requested that the Final Monograph be revised to add clotrimazole 1% as a generally recognized safe and effective active ingredient for the treatment of athlete's foot, jock itch, and ringworm and for use in the treatment of superficial skin infections caused by yeast (*Candida albicans*). The latter indication is to be used only in labeling provided to health professionals.

Reference is also made to a letter by Dr. Debra Bowen, Director, Division of OTC Drug Products, dated September 18, 1997 requesting additional information to make a final decision on our request, and our responses submitted April 1, 1998, June 29, 1998 and July 2, 1998.

At this time, SPHCP is amending the citizen petition by removing the request for professional labeling "...for use in the treatment of superficial skin infections caused by yeast (*Candida albicans*).” Please be advised that all other requests in the citizen petition remain the same.

If you have any questions, please contact me at (908) 604-1560.

Sincerely,

Linval A.M. Francis
Associate Director, Regulatory Affairs

cc: Mr. Gerald Rshanow

96P-0460

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